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Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' MOTION AND
MEMORANDUM IN SUPPORT TO
SEAL CERTAIN TRIAL EXHIBITS**

(Assigned to the Honorable David G.
Campbell)

Pursuant to the Court's Protective Order in this case [ECF No. 269], Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") hereby respectfully move this Court for an order sealing certain exhibits entered into evidence during the *Booker v. Bard* trial. There are compelling reasons to find that the documents contain information that is both proprietary and confidential and that Bard would suffer severe prejudice and injury if the information was made public. As a result, Bard respectfully requests that the Court seal the exhibits identified in Exhibit A, attached hereto.

I. FACTUAL BACKGROUND

Attached as Exhibit A is a chart of the exhibits entered into evidence during trial that Bard has designated as falling within certain categories of documents that should be sealed, as discussed further below (the “Documents”). Although the exhibits are not available publicly, counsel in the *Booker* case takes the position that because they were admitted into evidence they are no longer governed by the Parties’ Protective Order. [ECF No. 269]. Bard moves to seal the Documents, all of which were produced to Plaintiff as Confidential pursuant to Section III of the Protective Order. This Protective Order provides that “[t]he use of Confidential Information during trial will be addressed in a later agreement between the parties, or, if they cannot reach an agreement, by further order of the Court.” [*Id.* at ¶ 28]. Bard requests an Order sealing the documents or alternatively finding that they remain protected by the Protective Order.

As described more thoroughly below, the Documents contain Bard’s confidential trade secrets and/or contains or reflect highly competitive, confidential, or proprietary information. The Documents are not made public by Bard and, if their content were obtained by Bard’s competitors, it would give an unfair economic advantage to those competitors.¹ The medical device industry for IVC filters is a highly technical and sophisticated industry. It is also a highly competitive industry in which each company carefully guards its company documents, data, systems, processes, research and development, and analysis from competitors. *See* Declaration of Robert Carr (“Carr Decl.”), attached as Exhibit B. This Court has already sealed similar documents in this litigation, including some of the exhibits in the Documents, which are separated into four categories of confidential and proprietary information that must be sealed to protect Bard’s financial and business interests.²

¹ Bard is seeking to seal the Documents only and not the transcript of the trial. While portions of the Documents were discussed during the trial, it is the full content of the documents that would reveal Bard’s trade secrets and confidential and proprietary information.

² Many of the documents were filed in connection with Bard’s Motion for Summary Judgment on Preemption and were sealed by the Court. [ECF Nos. 7787, 9692].

1 The first category of the Documents Bard seeks to seal relates to product testing.
 2 These include numerous test reports regarding bench and animal testing conducted as part
 3 of Bard's development of its IVC filters. A few representative examples include Exhibit
 4 1578, "ETR-06-28-29, revision 0, project #8049, Caudal Migration Test Method
 5 Development and G2 Filter Resistance Test Report"; Exhibit 5233, "RD-SOP-054.00
 6 (Recovery Filter EnduraTEC Fatigue Testing SOP NMT)"; and Exhibit 5304, "ETR-05-
 7 02-11 G1A Recovery Filter Femoral System Chronic Animal Study Report." This
 8 category of documents must be sealed to preserve Bard's competitive advantage in the
 9 medical device market. Bard has spent a great deal of time and considerable sums of
 10 money developing and implementing a robust, confidential product testing regime of its
 11 filter products, a regime that is central to its product development and which largely has
 12 remained consistent since its implementation during the Recovery® era, including during
 13 the development of the Denali filter which is still on the market. Thus, for Bard's
 14 competitors to have access to Bard's confidential testing regime would provide them
 15 insight into Bard's current testing regime, and therefore Bard's confidential, proprietary
 16 business operations. This would cause Bard irreparable harm and would place Bard's
 17 competitors at a competitive advantage in the marketplace.

18 The second category of exhibits in the Documents that Bard seeks to seal relates
 19 non-testing product design and development materials. These include design reviews,
 20 product franchise reviews, financial analysis and projections, design proposals, and
 21 documents regarding other similar proprietary business operations. A few representative
 22 examples include Exhibit 5315, "Phase 3 Design Review G1A Recovery Filter Femoral
 23 Delivery System"; Exhibit 945, "Monthly Report, IVC Filters/Covered Stents, April
 24 2004"; Exhibit 1062, "BPV/AngioMed New Product Development Review Meeting –
 25 April 26, 2004"; and Exhibit 5296, "G2 Filter Product Performance Specification, v.2."
 26 The exhibits contained in this category of the Documents also must be sealed to preserve
 27 Bard's competitive advantage in the highly competitive medical device market. Bard has
 28 invested heavily in research and development of its inferior vena cava filter products. This

1 extensive, confidential research and development is detailed in the exhibits contained in
2 this category of the Documents. Bard does not have access to its competitors' design and
3 development documents, so to provide Bard's competitors access to Bard's confidential
4 and proprietary product design and development documents would place them at a
5 competitive advantage over Bard in the marketplace, causing Bard irreparable harm.

6 The third category of exhibits in the Documents that Bard seeks to seal relates to
7 Bard's quality system procedures, complaint and adverse event responses, reporting and
8 handling, device tracking procedures, and corrective action procedures, particularly as it
9 relates to complaint analysis and/or trending regarding the G2® Filter, the G2®X Filter,
10 and the Recovery® Filter. Representative examples include Exhibit 2052, "G2 and G2X
11 Fracture Analysis – 11/30//2008"; Exhibit 2245, "Recovery (Gen 1) – Fracture and
12 Migration Complaint Update – 6/20/2006"; and Exhibit 2217, "IVC Filters Retrospective
13 Review," a review and analysis of two years of filter complaints between 2013 and 2015.
14 Bard's complaint tracking and trending analysis is central to its ability to develop its
15 products successfully. Again, Bard does not have access to its competitors' quality system
16 procedures and complaint and trending analyses, so providing Bard's competitors this
17 crucial, confidential information about Bard's products would put Bard's competitors at a
18 decided advantage at the marketplace.

19 The final category of exhibits in the Documents that Bard seeks to seal relates to
20 FDA submissions and FDA contacts discussing Bard's products, including
21 communications between Bard and FDA as part of the confidential portion of the 510(k)
22 clearance process and post-market communications. These documents contain much of
23 the same confidential testing and design information that Bard submitted to the FDA.
24 Representative examples include Exhibit 5189, the July 10, 2002, IMPRA Recovery
25 Permanent Special 510(k) (K022236); Exhibit 5195, a November 30, 2004, Letter from
26 the FDA to Bard regarding the Recovery IFU and Dear Doctor Letter; and Exhibit 5335,
27 and an August 23, 2007, Letter from Bard to the FDA regarding the G2 Everest Study
28 Annual Progress Report. The exhibits in this category of the Documents contain

confidential, proprietary information provided to the FDA in communications that was not intended to be made public, the dissemination of which would lead to Bard's competitors gaining an upper hand in the marketplace, as Bard does not have access to similar information, documents, or communications belonging to its competitors.

II. ARGUMENT AND CITATION OF AUTHORITY

A. Legal Standard for Sealing Documents With Bard's Confidential Information.

While compelling reasons must be shown to seal exhibits at trial, even under this higher, compelling reasons sealing standard, the Court should still consider "whether disclosure of the material could result in improper use of the material for scandalous or libelous purposes or infringement upon trade secrets." *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006); *In re Elec. Arts, Inc.*, 298 F. App'x 568, 569 (9th Cir. 2008) ("[T]he district court correctly concluded that the legal principles set forth in *Kamakana v. City and County of Honolulu*, 447 F.3d 1172, 1178 (9th Cir.2006), control the decision whether to seal paragraph 6 of Trial Exhibit 80 from public access."); *Brock v. Skolnik*, 3:11-CV-00086-ECR, 2011 WL 6026298 at *2 (D. Nev. Dec. 2, 2011) (quoting *Pintos v. Pacific Creditors Ass'n*, 605 F.3d 665, 678 (9th Cir.2010)). Moreover, where, as here, a party produces confidential documents in reliance on a confidentiality agreement between the parties, this reliance weighs in favor of finding confidentiality, although such production in reliance on a confidentiality agreement does not, on its own, require the sealing of those documents. *See In re Denture Cream Prods. Liab. Litig.*, Civil Action No. 09-2051-MD, 2013 WL 214672, at *10 (S.D. Fla. Jan. 18, 2013); *see also*, *Phillips ex rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206, 1213 (9th Cir. 2002) ("When a court grants a protective order for information produced during discovery, it already has determined that 'good cause' exists to protect this information from being disclosed to the public by balancing the needs for discovery against the need for confidentiality."). As discussed below, Bard has a compelling interest in maintaining the confidentiality of its proprietary and trade secret information, which, if disclosed to the

1 public and Bard's competitors, would cause harm to Bard. Accordingly, Bard respectfully
 2 requests that the Court seal the Documents.

3 **B. There Are Compelling Reasons To Preserve Proprietary Information in**
 4 **the Documents.**

5 The compelling reasons standard is met in this case by showing that public
 6 disclosure of the documents will cause a clearly defined and serious injury to Bard.
 7 "Where the material includes information about proprietary business operations, a
 8 company's business model or agreements with clients, there are compelling reasons to
 9 seal the material because possible infringement of trade secrets outweighs the general
 10 public interest in understanding the judicial process." *Selling Source, LLC v. Red River*
 11 *Ventures, LLC*, 2:09-CV-01491-JCM, 2011 WL 1630338 (D. Nev. Apr. 29, 2011). The
 12 Protective Order in this case states "All Confidential Information shall be used only for
 13 the purpose of this lawsuit only . . . except as permitted by this Order." [ECF No. 269, ¶
 14 12]. These types of provisions are common in legal proceedings and are routinely
 15 enforced. *See Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 307 (N.D. Ill.
 16 1993) ("We hold that confidential information obtained by Culinary in this litigation may
 17 not be disseminated to litigants in other cases against Raychem."); *cf Smithkline Beecham*
 18 *Corp. v. Synthon Pharmaceuticals Ltd.*, 210 F.R.D. 163, 169 (M.D.N.C. 2002) (refusing to
 19 modify protective order to allow plaintiffs to use confidential documents in other
 20 litigation).

21 Courts have long recognized that the four categories of exhibits in the Documents
 22 contain information that requires sealing to protect Bard's financial and business interests.
 23 Courts in the Ninth Circuit, including in the District of Arizona, have consistently held
 24 that documents containing confidential business information, like the first three categories
 25 identified above, should be sealed. *See e.g., Bean v. Pearson Educ., Inc.*, No. CV 11-
 26 8030-PCT-PGR, 2013 WL 2455930, at *2 (D. Ariz. June 5, 2013) ("Compelling reasons
 27 to seal a typically exist when such court files might become "a vehicle for improper
 28 purposes, such as the use of records to . . . release trade secrets."); *TriQuint*

1 *Semiconductor, Inc. v. Avago Techs. Ltd.*, No. CV 09-1531-PHX-JAT, 2011 WL
 2 4947343, at *2 (D. Ariz. Oct. 18, 2011), on reconsideration, No. CV 09-1531-PHX-JAT,
 3 2011 WL 5190264 (D. Ariz. Nov. 1, 2011) (in holding that a party had shown compelling
 4 reasons for sealing, noting that “[w]here a party shows that its documents contain sources
 5 of business information that might harm its competitive standing, the need for public
 6 access to the records is lessened.”); *Clark v. Metro. Life Ins. Co.*, 2010 WL 1006823 (D.
 7 Nev. Mar. 16, 2010) (sealing “confidential internal business deliberations, organization,
 8 and capabilities”); *JL Beverage Co., LLC v. Beam, Inc.*, 2013 WL 1088363 (D. Nev. Mar.
 9 14, 2013) *reconsideration denied*, 2013 WL 3027453 (D. Nev. June 14, 2013) (sealing
 10 “sales figures, advertising numbers, and strategy information relating to Defendants’
 11 Pucker Vodka line of products”); *Medicis Pharm. Corp. v. Acella Pharm., LLC*, CV 10-
 12 1780-PHX-JAT, 2012 WL 2260928 at *2 (D. Ariz. June 15, 2012) (sealing exhibits
 13 related to “Medicis’ marketing strategy, Acella’s product formulation,...various emails
 14 and deposition transcripts, viscosity test data, sales and marketing information, and
 15 various other documents” because “[m]uch of this information has been previously sealed
 16 by the Court, has been designated as confidential by the parties pursuant to the protective
 17 order in this case, or could otherwise potentially harm the parties if released publicly
 18 because of its confidential and sensitive nature.”).

19 Courts in the Ninth Circuit have also held that FDA communications and
 20 documents, which are contained in the fourth category of the Documents, warrant sealing.
 21 *Spectrum Pharm., Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at
 22 *2 (D. Nev. Aug. 21, 2014) (sealing among other “proprietary business plans” and
 23 “business practices,” “actual and planned confidential communications with the FDA”);
 24 *Citizens Comm’n on Human Rights v. Food & Drug Admin.*, 1993 WL 1610471, *7
 25 (C.D.Cal.1993) (A drug application to FDA “by definition contains trade secret
 26 information because it contains significant information about how a...drug product is
 27 formulated, chemically composed, manufactured, and quality controlled.”), *aff’d in part &*
 28 *remanded in part on other grounds*, 45 F.3d 1325 (9th Cir.1995); *see also, Bracco*

1 *Diagnostics, Inc. v. Amersham Health Inc.*, CIVA 3-6025FLW, 2007 WL 2085350
 2 (D.N.J. July 18, 2007) (sealing “regulatory correspondence” with the FDA, “cost and
 3 profit information,” “unpublished clinical studies,” and “internal analyses on products
 4 which are not intended for publication or dissemination”).

5 Importantly, courts in the Ninth Circuit have found that documents in these
 6 categories should remain sealed even after being used at trial. For example, in *Livingston*
 7 *v. Isuzu Motors, Ltd.*, 910 F. Supp. 1473, 1480 (D. Mont. 1995), the court found that
 8 although exhibits were used at trial, they never remained with the clerk of court and were
 9 not made part of “the public record as it existed following the trial.” The court further
 10 noted that “during the trial these documents were regarded by all parties as confidential,
 11 sensitive information, and by implication agreed that the untoward release of them had the
 12 potential to harm defendants. Finally, the confidential documents are not now part of the
 13 public record; the continued treatment of the documents as confidential will not impose a
 14 burden upon any party to this action.” *Id.* The court relied on an opinion in related
 15 litigation sealing similar exhibits, *Jochims v. Isuzu Motors, Ltd.*, 151 F.R.D. 338, 341
 16 (S.D. Iowa 1993). In that case, the court sealed trial exhibits including “internal
 17 engineering standards, confidential information regarding advertising expenditures, and
 18 test reports relating to the design and development of the Trooper. They are the kind of
 19 technical and commercial information commonly subject to confidentiality orders in cases
 20 of this kind. Depriving these documents of their confidential status would be inimical to
 21 Isuzu's competitive interests.” *Id.* As a result, the categories of trial exhibits identified
 22 above and in Exhibit A should be sealed.

23 Sealing each category of information listed above is further warranted in this case
 24 because Bard has continually and successfully made efforts to protect the information
 25 from its competitors, in part because it could be used by competitors against Bard. *See In*
 26 *re Denture Cream Products Liab. Litig.*, 09-2051-MD, 2013 WL 214672 (S.D. Fla. Jan.
 27 18, 2013) (finding documents confidential in part because the defendant “consistently
 28 treated the information as closely guarded secrets”); [*See* ECF No. 269; Ex. B, Carr Decl.]

The Documents reflect confidential and proprietary information concerning the design, development, testing (including clinical testing), and regulatory compliance activities concerning Bard's IVC filters; that detail Bard's product development activities, proprietary testing, and implementation of various proprietary processes and procedures. [Ex. B, Carr Decl. ¶ 3, 10]. The information in the Documents took years for Bard to develop and reflects Bard's crucial and confidential business information. [*Id.* at ¶ 11-13]. Moreover, the information contained in the Documents would be of economic value to Bard's competitors. [*Id.*]. Bard invests substantial amounts of money in medical device research, testing, clinical trials, development, design, analysis, regulatory compliance, and evaluation. [*Id.*]. Thus, if Bard's competitors obtained the Documents, they would have an unfair economic advantage over Bard.

Finally, Bard invests substantial sums of money in medical device research, testing, development, design, analysis, regulatory compliance, and evaluation of its products and does not make such information public. Thus, there is no doubt that the proprietary information that Bard seeks to protect constitutes an overriding interest warranting protection.

C. The Resulting Prejudice From Public Disclosure Requires This Court's Protection

As stated above, the Documents contain highly confidential and sensitive information about Bard's design, product development, and testing of its filters, and allowing unrestricted access to this information would cause real and tangible harm to Bard. *See e.g., In re Eli Lilly & Co., Prozac Products Liability Litigation*, 142 F.R.D. 454, 460 (S.D. Ind. 1992) (holding pharmaceutical company would suffer harm if the manufacturing process it has expended time and money developing became known to competitors); *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 305 *order clarified*, 153 F.R.D. 614 (N.D. Ill. 1993) ("[D]isclosing Raychem's product design modification and changes would decrease Raychem's incentive to invest in safety devices.

1 Raychem's competitors would get free access to information which Raychem has spent a
2 great deal of time and money producing and protecting").

3 It is well documented that the current market for pharmaceuticals and medical
4 devices is highly competitive. *See, e.g., In re Gabapentin Patent Litigation*, 312 F. Supp.
5 2d 653, 659 (D.N.J. 2004) (noting the pharmaceutical industry is highly competitive and
6 granted protective order). To remain competitive, Bard has invested great amounts of time
7 and considerable sums of money over the past decades in medical device research, testing,
8 development, design, analysis, regulatory compliance, and evaluation. This heightened
9 level of competitiveness in the medical device market warrants protecting Bard's efforts
10 in developing such precise and valuable medical devices, such as the Bard Filters at issue
11 here. There is no valid reason for Bard's competitors to obtain the results of Bard's
12 extensive product testing and development without having to incur similar expenditures in
13 time and money, since it would give them an unfair economic advantage in this highly
14 competitive marketplace. Any disclosure of Bard's information to any of its competitors
15 through open court records would certainly injure Bard's interest and standing in the
16 marketplace. Therefore, Bard respectfully requests that the Court seal the Documents. *See,*
17 *e.g., In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653 (holding that evidence
18 supported finding that good cause existed for continued secrecy of materials).

19 CONCLUSION

20 The public disclosure of the Documents would reveal confidential, proprietary, and
21 trade secret information and would create a heightened risk of irreparable harm to Bard's
22 competitive business concerns. Further, the Documents' inclusion in the public record
23 would not only harm Bard because of the trade secrets and confidential information it
24 contains, but it would also eviscerate the significant time and resources Bard has
25 expended in protecting its business information. The potential for abuse and for
26 competitive loss are real. Accordingly, Defendants request that the exhibits identified in
27 Exhibit A be sealed.

1 RESPECTFULLY SUBMITTED this 7th day of May, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of May, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.
Richard B. North, Jr.